

§ 1310.06

(d) Each regulated bulk manufacturer of a listed chemical shall submit manufacturing, inventory and use data on an annual basis as set forth in §1310.06(h). This data shall be submitted annually to the Drug and Chemical Evaluation Section, Drug Enforcement Administration (DEA), Washington, D.C. 20537, on or before the 15th day of March of the year immediately following the calendar year for which submitted. A business entity which manufactures a listed chemical may elect to report separately by individual location or report as an aggregate amount for the entire business entity provided that they inform the DEA of which method they will use. This reporting requirement does not apply to drug or other products which are exempted under §§1310.01(f)(1)(iv) or 1310.01(f)(1)(v) except as set forth in §1310.06(h)(5). Bulk manufacturers that produce a listed chemical solely for internal consumption shall not be required to report for that listed chemical. For purposes of these reporting requirements, internal consumption shall consist of any quantity of a listed chemical otherwise not available for further resale or distribution. Internal consumption shall include (but not be limited to) quantities used for quality control testing, quantities consumed in-house or production losses. Internal consumption does not include the quantities of a listed chemical consumed in the production of exempted products. If an existing standard industry report contains the information required in §1310.06(h) and such information is separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report shall be submitted to the DEA under company letterhead and signed by an appropriate, responsible official. For purposes of this paragraph only, the term regulated bulk manufacturer of a listed chemical means a person who manufactures a listed chemical by means of chemical synthesis or by extraction from other substances. The term bulk manufacturer does not include persons whose sole activity consists of the repackaging or relabeling of listed chemical products or the manufacture of

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drug dosage form products which contain a listed chemical.

[54 FR 31665, Aug. 1, 1989, as amended at 57 FR 2461, Jan. 22, 1992; 61 FR 14024, Mar. 29, 1996; 61 FR 17958, Apr. 23, 1996; 62 FR 13968, Mar. 24, 1997]

EFFECTIVE DATE NOTE: At 67 FR 14862, Mar. 28, 2002, §1310.05 was amended by adding paragraph (e), effective Apr. 29, 2002. For the convenience of the user, the added text follows:

§ 1310.05 Reports.

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(e) Each regulated person required to report pursuant to §1310.03(c) of this part shall either:

(1) Submit a written report, containing the information set forth in §1310.06(i) of this part, on or before the 15th day of each month following the month in which the distributions took place. The report shall be submitted under company letterhead, signed by the person authorized to sign the registration application forms on behalf of the registrant, to the Chemical Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; or

(2) Upon request to and approval by the Administration, submit the report in electronic form, either via computer disk or direct electronic data transmission, in such form as the Administration shall direct. Requests to submit reports in electronic form should be submitted to the Chemical Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, ATTN: Electronic Reporting.

§ 1310.06 Content of records and reports.

(a) Each record required by §1310.03 shall include the following:

(1) The name, address, and, if required, DEA registration number of each party to the regulated transaction.

(2) The date of the regulated transaction.

(3) The name, quantity and form of packaging of the listed chemical or a description of the tableting machine or encapsulating machine (including make, model and serial number).

(4) The method of transfer (company truck, picked up by customer, etc.).

(5) The type of identification used by the purchaser and any unique number on that identification.

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(b) For purposes of this section, normal business records shall be considered adequate if they contain the information listed in paragraph (a) of this section and are readily retrievable from other business records of the regulated person. For prescription drug products, prescription and hospital records kept in the normal course of medical treatment shall be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to dispensing to patients, and records required to be maintained pursuant to the Federal Food and Drug Administration regulations relating to the distribution of prescription drugs, as set forth in 21 CFR part 205, shall be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to distributions.

(c) Each report required by Section 1310.05(a) shall include the information as specified by Section 1310.06(a) and, where obtainable, the registration number of the other party, if such party is registered. A report submitted pursuant to §1310.05(a)(1) or (a)(4) must also include a description of the circumstances leading the regulated person to make the report, such as the reason that the method of payment was uncommon or the loss unusual. If the report is for a loss or disappearance under §1310.05(a)(4), the circumstances of such loss must be provided (in-transit, theft from premises, etc.)

(d) A suggested format for the reports is provided below:

Supplier:

Registration Number _____
Name _____
Business Address _____
City _____
State _____
Zip _____
Business Phone _____

Purchaser:

Registration Number _____
Name _____
Business Address _____
City _____
State _____
Zip _____
Business Phone _____
Identification _____

Shipping Address (if different than purchaser Address):

Street _____
City _____
State _____
Zip _____
Date of Shipment _____
Name of Listed Chemical(s) _____
Quantity and Form of Packaging _____

Description of Machine:

Make _____
Model _____
Serial # _____
Method of Transfer _____

If Loss or Disappearance:

Date of Loss _____
Type of Loss _____
Description of Circumstances _____

Public reporting burden for this collection of information is estimated to average ten minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Drug Enforcement Administration, Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0024, Washington, D.C. 20503.

(e) Each report of an importation of a tableting machine or an encapsulating machine required by §1310.05(c) shall include the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the regulated person; the name, address, telephone number, telex number, and, where available, the facsimile number of the import broker or forwarding agent, if any;

(2) The description of each machine (including make, model, and serial number) and the number of machines being received;

(3) The proposed import date, and the first U.S. Customs Port of Entry; and

(4) The name, address, telephone number, telex number, and, where available, the facsimile number of the

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consignor in the foreign country of exportation.

(f) Each report of an exportation of a tableting machine or an encapsulating machine required by § 1310.05(c) shall include the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the regulated person; the name, address, telephone number, telex number, and, where available, the facsimile number of the export broker, if any;

(2) The description of each machine (including make, model, and serial number) and the number of machines being shipped;

(3) The proposed export date, the U.S. Customs Port of exportation, and the foreign Port of Entry; and

(4) The name, address, telephone, telex, and, where available, the facsimile number of the consignee in the country where the shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

(g) Declared exports of machines which are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. exporter of record. A brief written report outlining the circumstances must be sent to the Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038, following the return within a reasonable time. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States will be regarded as imports.

(h) Each annual report required by Section 1310.05(d) shall provide the following information for each listed chemical manufactured:

(1) The name, address and chemical registration number (if any) of the manufacturer and person to contact for information.

(2) The aggregate quantity of each listed chemical that the company manufactured during the preceding calendar year.

(3) The year-end inventory of each listed chemical as of the close of business on the 31st day of December of each year. (For each listed chemical, if the prior period's ending inventory has not previously been reported to DEA,

this report should also detail the beginning inventory for the period.) For purposes of this requirement, inventory shall reflect the quantity of listed chemicals, whether in bulk or non-exempt product form, held in storage for later distribution. Inventory does not include waste material for destruction, material stored as an in-process intermediate or other in-process material.

(4) The aggregate quantity of each listed chemical used for internal consumption during the preceding calendar year, unless the chemical is produced solely for internal consumption.

(5) The aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted from Section 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) during the preceding calendar year.

(6) Data shall identify the specific isomer, salt or ester when applicable but quantitative data shall be reported as anhydrous base or acid in kilogram units of measure.

[54 FR 31665, Aug. 1, 1989, as amended at 57 FR 2462, Jan. 22, 1992; 59 FR 51364, Oct. 11, 1994; 60 FR 32461, June 22, 1995; 61 FR 14024, Mar. 29, 1996; 61 FR 32926, June 26, 1996]

EFFECTIVE DATE NOTE: At 67 FR 14862, Mar. 28, 2002, § 1310.06 was amended by adding paragraphs (i) and (j), effective Apr. 29, 2002. For the convenience of the user, the added text follows:

§ 1310.06 Content of records and reports.

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- (i) Each monthly report required by § 1310.05(e) of this part shall provide the following information for each distribution:
- (1) Supplier name and registration number.
 - (2) Purchaser's name and address.
 - (3) Name/address shipped to (if different from purchaser's name/address).
 - (4) Name of the chemical and total amount shipped (i.e. Pseudoephedrine, 250 grams).
 - (5) Date of shipment.
 - (6) Product name (if drug product).
 - (7) Dosage form (if drug product) (i.e., pill, tablet, liquid).
 - (8) Dosage strength (if drug product) (i.e., 30mg, 60mg, per dose etc.).
 - (9) Number of dosage units (if drug product) (100 doses per package).
 - (10) Package type (if drug product) (bottle, blister pack, etc.).
 - (11) Number of packages (if drug product) (10 bottles).
 - (12) Lot number (if drug product).

(j) Information provided in reports required by § 1310.05(e) of this part which is exempt from disclosure under section 552(a) of Title 5, by reason of section 552(b)(6) of Title 5, will be provided the same protections from disclosure as are provided in section 310(c) of the Act (21 U.S.C. 830(c)) for confidential business information.

§ 1310.07 Proof of identity.

(a) Each regulated person who engages in a regulated transaction must identify the other party to the transaction. For domestic transaction, this shall be accomplished by having the other party present documents which would verify the identity, or registration status if a registrant, of the other party to the regulated person at the time the order is placed. For export transactions, this shall be accomplished by good faith inquiry through reasonably available research documents or publicly available information which would indicate the existence of the foreign customer. No proof of identity is required for foreign suppliers.

(b) The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting machine or encapsulating machine. For domestic transactions, this may be accomplished by such methods as checking the telephone directory, the local credit bureau, the local Chamber of Commerce or the local Better Business Bureau, or, if the business entity is a registrant, by verification of the registration. For export transactions, a good faith inquiry to verify the existence and apparent validity of a foreign business entity may be accomplished by such methods as verifying the business telephone listing through international telephone information, the firm's listing in international or foreign national chemical directories or other commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, verification through the country of destination's embassy Commercial Attache, or official documents provided by the purchaser which confirm the existence and apparent validity of the business entity.

(c) When transacting business with a new representative of a firm, the regu-

lated person must verify the claimed agency status of the representative.

(d) For sales to individuals or cash purchasers, the type of documents and other evidence of proof must consist of at least a signature of the purchaser, a driver's license and one other form of identification. Any exports to individuals or exports paid in cash are suspect and should be handled as such. For such exports, the regulated person shall diligently obtain from the purchaser or independently seek to confirm clear documentation which proves the person is properly identified such as through foreign identity documents, driver's license, passport information and photograph, etc. Any regulated person who fails to adequately prove the identity of the other party to the transaction may be subject to the specific penalties provided for violations of law related to regulated transactions in listed chemicals.

(e) For a new customer who is not an individual or cash customer, the regulated person shall establish the identity of the authorized purchasing agent or agents and have on file that person's signature, electronic password, or other identification. Once the authorized purchasing agent has been established, the agent list may be updated annually rather than on each order. The regulated person must ensure that shipments are not made unless the order is placed by an authorized agent of record.

(f) With respect to electronic orders, the identity of the purchaser shall consist of a computer password, identification number or some other means of identification consistent with electronic orders and with § 1310.07(e).

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32461, June 22, 1995]

§ 1310.08 Excluded transactions.

Pursuant to 21 U.S.C. 802(39)(A)(iii), regulation of the following transactions has been determined to be unnecessary for the enforcement of the Chemical Diversion and Trafficking Act and, therefore, they have been excluded from the definitions of regulated transactions:

(a) Domestic and import transactions of hydrochloric and sulfuric acids but